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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,199	01/04/2002	Gregory Newton Brewer	P 284145	2505
23117	7590	05/27/2005	EXAMINER	
NIXON & VANDERHYE, PC			PATEL, MITAL B	
901 NORTH GLEBE ROAD, 11TH FLOOR			ART UNIT	
ARLINGTON, VA 22203			PAPER NUMBER	

3743

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,199

Applicant(s)

BREWER ET AL.

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-73 is/are pending in the application.
- 4a) Of the above claim(s) 29-56 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 63, 67-68 is/are allowed.
- 6) ☒ Claim(s) 27, 28, 57-62, 64-66 and 69-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's arguments regarding the rejoinder of claims 29-56 have been considered but have been found to be non-persuasive. Claims 29-56 do not require that the method be performed in the automatic titration.

The requirement is still deemed proper and is therefore made FINAL.

Response to Amendment/Arguments

2. Applicant's arguments filed 3/4/05 have been fully considered but they are not persuasive.

3. In response to Applicant's arguments that Estes et al. does not teach a test pressure that is not related to the pressures which are encountered by the patient during a normal test session. However, the peak pressure or the minimum pressure outputted by the apparatus during the previous night may very well encompass the pressures encountered during normal use. Furthermore, Estes et al. teaches that the test pressure could be some other desired pressure, which would include the pressures encountered during normal use.

4. Furthermore, Applicant argues that the test pressure is similar in magnitude to pressures encountered during normal use but the claim recites "similar in magnitude to normal pressures encountered during the prior treatment session." It is not clear to the Examiner what exactly constitutes "normal pressure" as pressures will vary based on

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the individual and the condition of the individual during the given time that the mask is used.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 27, 28, 57-62, 64, 65, 66, 69, 70-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has not provided support in the specification as originally filed with respect to "said mask-fit test pressure being substantially similar in magnitude to normal pressures encountered during the prior treatment session."

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 27 and 57-62, 64, 66, 69, and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Estes et al (US 5,901,704).

9. **As to claim 27**, Estes et al teaches a method for determining a mask-fit test pressure to be applied to a wearer's mask by ventilatory assistance apparatus, wherein the mask-fit pressure is adaptively dependent on a prior pressure treatment session of the wearer, said mask-fit test pressure being substantially similar in magnitude to normal pressures encountered during the prior treatment session (**See Col. 30, lines 8-65; please note the prior pressure treatment session is taught in lines 25-30; it should be noted that the peak pressure and low pressure would be encompassed in the recitation of normal pressures since Applicant has not disclosed what constitutes normal pressures**).

10. **As to claim 57**, Estes et al teaches a method wherein the mask-fit pressure is determined based on a prior use by comparing leak flow to a threshold leak flow value (**See Col. 30, lines 8-65**).

11. **As to claim 58**, Estes et al teaches a method wherein the leak flow is determined over a predetermined time period (**See Col. 3, lines 31-36**).

12. **As to claim 60**, Estes et al teaches a method for determining a mask-fit test pressure to be applied to a wearer's mask by ventilatory assistance apparatus (**See Col. 30, lines 8-65**) wherein the method is practiced with a CPAP device having two functional modes (**See Col. 29, lines 27-61**).

13. **As to claim 61**, Estes et al teaches a method wherein determining the mask-fit pressure includes sampling pressure signals in a gas supply assembly associated with the mask (**See Col. 30, lines 35-38**).
14. **As to claim 62**, Estes et al teaches a method wherein sampling pressure signals occurs in a delivery tube (**See Col. 30, lines 35-38**) of the gas supply assembly.
15. **As to claim 64**, Estes et al teaches a method wherein sampling pressure signals occurs at predetermined intervals (**See Col. 30, lines 8-65**).
16. **As to claim 66**, Estes et al teaches a method wherein sampling pressure signals includes determining a flow of gas in the mask and generating a delivery pressure signal (**See Col. 30, lines 35-38**).
17. **As to claim 69**, Estes et al teaches a method further comprising varying at least one setting relating to test pressure intervals, test pressure period, and determined test pressure (**See Col. 30, lines 35-38**).
18. **As to claim 72**, Estes et al teaches a method wherein pressure data from said prior treatment session is available if the prior treatment pressure occurred for at least a predetermined time interval (**See Col. 29-30**).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 59, 65, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes et al (US 5,901,704)

21. **As to claims 59 and 65**, Estes et al teaches essentially all of the limitations except for the specific time values. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the time period of several seconds as taught by Estes et al because Applicant has not disclosed that the claimed time values provides an advantage, is used for a particular purpose, or solves a stated problem or provides unexpected results. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the time value taught by Estes et al because the method for determining a mask-fit is not altered by the time value. Therefore, it would have been an obvious matter of design choice to modify the method of Estes et al to obtain the invention as specified in claim 59 and 65

Allowable Subject Matter

22. Claims 63, 67-68 are allowed over the prior art of record.

23. The following is a statement of reasons for the indication of allowable subject matter: As to claim 63, the prior art of record does not teach nor render obvious the overall claimed combination of a method for determining a mask-fit test pressure wherein the sampling of pressure signals occurs in a blower of the gas supply assembly. As to claim 67, the prior art of record does not teach nor render obvious the


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overall claimed combination of a method for determining a mask-fit test pressure wherein determining the mask-fit pressure also includes processing the sampled pressure signals and producing a control signal based on the processed signals, wherein the control signal is provided to a motor to provide a determined treatment pressures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 5/26/05
Mital B. Patel
Examiner
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